

SEP 20 2006

Application No.: 10/772,915

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Docket No.: 297912003410

REMARKS

The Office Action dated August 8, 2006 has been reviewed and the Examiner's comments considered. Claims 1-16 are pending in this application. Applicants appreciate the Examiner's withdrawal of the rejection of claim 10 under 35 U.S.C. § 112, ¶ 2.

Claim Rejections - 35 U.S.C. § 102

Claims 1-5 and 9-12 stand rejected under 35 U.S.C. § 102(e) as being anticipated by USPN 6,187,054 to Colone et al. Applicants respectfully traverse this rejection.

Rebuttal to Response to Arguments

In the Amendment filed June 6, 2006, Applicants set forth the following with respect to the rejected independent claims 1 and 9:

"Independent claim 1 recites, *inter alia*, "heating said calendered tube above the crystalline melt-point for polytetrafluoroethylene while maintaining said second inner diameter substantially constant." Independent claim 9 recites, *inter alia*, "heating said calendered tube above the crystalline melt-point for polytetrafluoroethylene while maintaining said first inner diameter substantially constant." In both independent claims, it is required to heat the calendered tube above the crystalline melt-point for polytetrafluoroethylene while the diameter of the tube is maintained substantially constant. In the case of claim 1, this step is performed following radial dilation to the second inner diameter (in other words, it is this second inner diameter that is maintained substantially constant, which doesn't allow for an intervening radial contraction step). In the case of claim 9, as amended, this step is performed at an extruded first inner diameter (which also doesn't allow for an intervening radial contraction step)."

(p. 7, Amendment of June 6, 2006, emphasis in original)

In the Response to Arguments on p. 8 of the final Office Action, after admitting that Colone et al. describes a radial contraction step (col. 5, lines 61-64), the Examiner, states that such a step is "no different than what takes place in practicing the pending claims." Further, the Examiner

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cites to paragraph [0021] of the instant application, apparently in support of this position. However, paragraph [0021] of the instant application states the following:

"After sufficient calendering of the ePTFE tubular graft wall has taken place, the loaded mandrel 100 is removed from the calendering device 110 and placed into a furnace, oven or other heating apparatus where it is heated above the crystalline melt point of PTFE in step 80 for a sufficient time to ensure that the entire structure is raised above this crystalline melt point. Once the heating cycle is complete, the graft is carefully removed from the mandrel in step 90."

(paragraph [0021] of the instant application).

Applicants respectfully submit that this passage does not discuss radial contraction of the graft, instead describing the step of heating the calendered graft above the crystalline melt point *while the diameter of the tube is maintained substantially constant*, as claimed and set forth in the June 6, 2006 Amendment, reproduced above. Thus, the Examiner's position that the claims and description in the instant application is the same as that described in Colone et al. with respect to radial contraction of a tube prior to sintering is untenable because the instant claims recite heating while maintaining the diameter of the tube substantially constant. Accordingly, Applicants respectfully request reconsideration of the Examiner's position.

Reply to Detailed Action

Claim 1 - In the Detailed Action, the Examiner states the following in support of the anticipation rejection of independent claim 1:

"Regarding claim 1, Colone et al. teach a method of producing an expanded polytetrafluoroethylene (ePTFE) structure comprising the steps of...calendering the radially expanded tube while maintaining its expanded second inner diameter (col. 5, lines 3-6), and heating the calendered tube at about 360° C while still disposed on the mandrel, ensuring the second inner diameter is substantially maintained constant (col. 5, line 65 – col. 6, line 2) to form a high density microwall ePTFE structure."

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(pp. 2-3, final Office Action dated August 8, 2006, emphasis added)

However, the Colone et al. passages cited in support of the Examiner's anticipation position actually describe something quite different, namely, a first mandrel 30 for calendaring and a second different mandrel 40 for first, pre-heating (to about 200° C) to radially contract, and second, sintering (at about 360° C, or above the crystalline melt point for PTFE) to set and cure:

"After the calendaring step 14, the tube 50' is removed from the mandrel 30. Steps 12 and 14 are repeated several times with larger and larger heated mandrels 30 (step 18) until a tube 54 is obtained which has a desired or targeted inner diameter (step 16), as determined by the last mandrel 30 used. At this point, the tube may be removed (step 20) and trimmed axially to a desired length L (step 22) as shown in FIG. 5....

The radially expanded tube resulting from steps 10-16 is used as a building block to make several types of prostheses, such as a graft with an encapsulated stent, a stent liner, etc....

Next, in step 204 the mandrel of FIG. 7C is inserted into an oven preheated to about 200° C. for about two minutes. This heating causes the tubes to soften, radially contract, and to lightly adhere to each other, and to mandrel 40. As a result, the tubes do not have to be restrained longitudinally. Next, in step 206, the mandrel and two tubes are sintered in an oven at about 360° C. for about 10 minutes. This step causes the tubes to be set to their final geometric shape and to cure together as a laminate."

(col. 5, line 23 to col. 6, line 2, Colone et al., emphasis added)

Thus, contrary to the Examiner's statement in the final Office Action, underlined above, Colone et al. does not show or describe the step of "heating said calendered tube above the crystalline melt-point for polytetrafluoroethylene while maintaining said second inner diameter substantially constant."

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Claim 9 - In the Detailed Action, the Examiner states the following in support of the anticipation rejection of independent claim 9

"Regarding claim 9, Colone et al. teach that tubes produced in an extruder (Abstract) with a variety of diameters can be made (col. 1, lines 26-29) and that depending on the final product, tubes of other diameters, and thicknesses may be made by the same process (col. 4, lines 8-10). Colone et al. further teach an iterative process until the desired diameter of the tube is achieved. Therefore, if the starting diameter of the tube were the desired final diameter it is clearly within the teaching and scope of Colone et al. that radially expanding the tube further would not be necessary and that the calendering would still be performed to provide strength (col. 2, lines 38-4)."

(pp. 3, final Office Action dated August 8, 2006, emphasis added)

However, contrary to the Examiner's conclusion, underlined above, Colone et al. shows and describes the production of thin-walled tubes through incremental dilation, specifically differentiating extruded thin-walled tubes. For example, Colone et al. states that tubes extruded with thin walls at extruded diameters are too fragile to be handled during processing (col. 1, line 66 to col. 2, line 3). Colone et al. goes on to state that the described invention is an improvement over such prior art extruded tubes (col. 2, lines 16-19). Colone et al. summarizes the invention as incremental dilation, followed by calendering, and finally radial contraction to a smaller diameter (col. 2, lines 33-42). Colone et al. again discusses gradual radial expansion of the initial tube resulting from the extrusion stage (col. 4, lines 13-17) and then reiterates the advantages of the incremental dilation process over prior art methods (col. 5, lines 30-33). Thus, it is definitely not "clearly within the teaching and scope of Colone et al. that radially expanding the tube further would not be necessary" as asserted by the Examiner.

Therefore, in view of the above, Applicants respectfully submit that Colone et al. does not show or describe either "heating said calendered tube above the crystalline melt-point for polytetrafluoroethylene while maintaining said second inner diameter substantially constant" (claim 1) or "heating said calendered tube above the crystalline melt-point for polytetrafluoroethylene

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while maintaining said first inner diameter substantially constant" (claim 9). Accordingly, claims 1 and 9 are patentable over Colone et al. Claims 2-5 and 10-12 are also patentable over the proposed combination because these claims depend from claims 1 and 9, and also recite other features not shown or described in Colone et al.

Claim Rejections - 35 U.S.C. § 103

Claims 6-8 and 13-15 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Colone et al., as applied to claims 1-5 and 9-12, in view of USPN 5,207,960 to Moret de Rocheprise. Claim 16 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Colone et al., as applied to claims 1-5 and 9-12, and further in view of USPAPN 2002/0183716 to Herweck et al. or USPN 6,016,848 to Egres, Jr. Applicants respectfully traverse these rejections.

Claims 6-8 and 16 are dependent on claim 1 and claims 13-15 are dependent on claim 9, each of which (claims 1 and 9) are believed to be patentable in view of the above. Accordingly, claims 6-8 and 13-16 are patentable for at least this reason.

Moreover, Moret de Rocheprise shows and describes the rolling of a tube between a set of three motor-driven wheels rotating around a mandrel, in which the three wheels are positioned at an angle thereto (col. 2, lines 7-18). Claims 6 and 13, however, recite, in part, placing a loaded mandrel between a first and second metallic plate maintained in a substantially parallel position. Moret de Rocheprise does not show or describe a first and second metallic plate. The Examiner admits that Colone et al. does not show or describe a first and second metallic plate (p. 5, final Office Action dated August 8, 2006). Therefore, a *prima facie* case of obviousness has not been established as set forth in MPEP § 2143.03 (MPEP 8th Ed., Rev. 2, August 2005), as all of the claimed features are not taught or suggested by the prior art.

The Examiner states that "adding an additional metallic plate to the single plate disclosed by Colone et al. for generating the press nip would have been obvious to the ordinarily skilled artisan" (p. 5, final Office Action dated August 8, 2006), but doesn't provide any basis for such a conclusion. Applicants request an objective reason why utilizing a second plate would have been

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obvious in view of Colone et al. Absent objective evidence for the provision of a second metallic plate in combination with Colone et al., claims 6 and 13 are not obvious and therefore patentable.

Finally, with respect to claim 16, the Examiner admits that Colone et al. does not show or describe radially expanding by positioning the ePTFE tube in a restraining tube set at a predetermined diameter, but then states that it would have been obvious in view of Herweck et al. or Egres, Jr. Applicants respectfully submit that, absent the benefit of Applicants' own disclosure, there is no suggestion or motivation to combine either Herweck et al. or Egres, Jr. with Colone et al. It is apparent from Colone et al. that the invention centers around incremental dilation of a tube through use of hot mandrels with progressively increasing diameters. Such a dilation procedure is incompatible with the claimed recitation of a restraining tube. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination (see MPEP § 2143.01 - MPEP 8th Ed., Rev. 2, August 2005). Accordingly, Applicants submit that a *prima facie* case of obviousness has not been established.

Therefore, claims 6-8 and 13-15 are patentable over Colone et al. in view of Moret de Rocheprise, and claim 16 is patentable over Colone et al. in view of Herweck et al. or Egres, Jr. for at least these reasons.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no.

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297912003410. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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